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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,924	07/15/2003	Gopi Venkatesh	451194-095	7145
27805	7590	02/13/2007		
THOMPSON HINE L.L.P. P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary**Application No.**

10/619,924

Applicant(s)

VENKATESH ET AL.

Examiner

Susan T. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicant's specification at page 12, paragraph 0031, while disclosed rapid dispersed upon contact with water, however, the specification does not appear to provide support for the limitation "the tablet rapidly disperses *into granules* on contact with water".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Sheth et al. US 4,954,349 or Remington.

Gantt teaches a process for preparing a controlled release potassium chloride (KCl) tablet comprising coating KCl particles with two coating layers by coacervation using polyethylene as a phase separator, blending the coated KCl particles with excipients, and then compressing the blended mixture into tablet (abstract; pages 3-4). First coating layer comprises ethyl cellulose having viscosity of about 90 to about 110 cp (page 3, 1st and 2nd paragraphs). Second coating layer comprises polyvinyl pyrrolidone, ethyl cellulose, hydroxypropylmethyl cellulose, or combination thereof (page 3, 3rd paragraph). Plasticizer such as triacetin, triethyl citrate, dibutyl sebacate, or PEG 400 is included in the second coating composition (page 3, 4th paragraph). Excipient includes binder, disintegrant (microcrystalline cellulose), wetting agent (surfactant), and lubricating agent (page 4, last paragraph through page 5, 1st paragraph).

Gantt does not explicitly teach the claimed silicon dioxide.

Sheth teaches a KCl compressed tablet comprising the use of lubricant including magnesium stearate and colloidal silicon dioxide (column 5, lines 54-56).

The Remington teaches ingredients for compressed tablet comprising binder, lubricant, disintegrant, and glidant including colloidal silicon dioxide (page 1619).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Gantt to use silicon dioxide as a glidant/lubricant/excipient in view of the teaching of Sheth or the Remington, because Sheth teaches the equivalency of magnesium stearate and silicon dioxide, because the Remington teaches the use of silicon dioxide in compressed tablet, and because Gantt

teaches the use of pharmaceutically acceptable excipient suitable for compressed tablet.

Gantt further does not expressly teach the claimed tablet hardness. However, the burden is shifted to applicant to show that the compressed tablet of Gantt does not exhibit the claimed properties, because Gantt uses the same ingredients in the same method using the same parameter for the same active, namely potassium chloride; and because Gantt teaches the compressed tablet having similar release profile, *e.g.*, not more than 40% in one hour and not less than 80% over 8 hours (page 5, 3rd paragraph).

Claims 6 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Sheth et al. US 4,954,349 or Remington, and Oshlack et al. US 5,472,712.

Gantt is relied upon for the reason stated above. Gantt does not teach the claimed plasticizing agent.

Oshlack teaches plasticizer includes diethyl phthalate, triethyl citrate, and triacetin (column 8, lines 34-40). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use diethyl phthalate as a plasticizing agent because Oshlack teaches the equivalency of diethyl phthalate with other well known plasticizing agent, and because Gantt teaches the use of other plasticizing agents in the compressed tablet formulation.

Response to Arguments

Applicant's arguments filed 11/13/06 have been fully considered but they are not persuasive.

Applicant argues that the comparative examples 1-3 in the present specification showed the differences between magnesium stearate and silicon dioxide. Therefore, Sheth cannot be combined with Gantt to obtain the claimed invention.

However, In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Gantt teaches the use of lubricant in the tablet formulation. Sheth teaches suitable lubricant includes silicon dioxide. Moreover, using silicon dioxide as a lubricant is well known in pharmaceutical art (see for example claims 11 and 20 of Gilinski; and column 4, lines 45-46 of Chiodini et al.). Accordingly, a skilled artisan would have been motivated to prepare Gantt's composition using silicon dioxide as a lubricant in view of the teaching of Sheth.

Applicant argues that claims 16 and 27 are believed to be separately patentable because the cited references fail to disclose or suggest preparation of a tablet that is substantially free of lubricants.

However, claims 16 and 27 appear contradicting to the subject matter of independent claims 1 and 20, because claims 1 and 20 require "silicon dioxide". As

discussed above, it is well known in pharmaceutical art that silicon dioxide is useful as a lubricant (see for example claims 11 and 20 of Gilinski; and column 4, lines 45-46 of Chiodini et al.).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-

0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran
Examiner
Art Unit 1615